

Rejections under 35 U.S.C. §112

Claims 1-68 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The examiner states that in claim 1 it is unclear what additional step is recited in the tightening step, given the relation already defined in the delivering step. Claim 1 has been amended to include tightening in the delivery step and the separate tightening step has been deleted.

The examiner states that it is unclear in claim 3 exactly what constitutes reduced cell necrosis. Accordingly, claim 3 has been amended to recite "while minimizing cell necrosis". This language is clear and precise and cell necrosis is well understood in the medical sciences.

The examiner has also stated that no further methods step is recited in claim 3-20. Applicant asserts that claims 3-20 further refine the method of claim 1, and as such, are considered allowable. Specifically claims 3-8 and 19 further refine the fifth step of claim 1. Claim 10 has been amended to add the step of "providing a source of electrolytic media coupled to the RF electrode" and claim 20 has been amended to add the step of "providing a cooling medium to cool the loose skin surface." Support for these amendments is found in the specification and claims as filed. Claims 11-12 provide further refinement of the step of providing a source of electrolytic media. Claims 9, 15-18 provide further refinement of the energy source in the second step of claim 1. Similar refinements were determined by the examiner to be definite in dependant method claims 3, 5 and 6 of US Patent No. 5,843,071 and dependant method claims 18-19 and 26-29 of US Patent No. 5,749,868 which provided recitation of structure only and/or further refinement of an energy source. Also the examiner determined that dependant method claims 21-23 and 30-32 of US No. 5,749,868 were definite when such claims only provided further refinement of a treatment site.

The examiner has stated that the recitation in claim 28 of the 'electrolytic media means' is indefinite as it recites no positive function. In response to this concern, claim 28 and subsequent claims have been amended to replace "electrolytic media means" with "RF energy conduction means". Support for these amendments is found in the specification and claims as filed.

Also with respect to claim 28, the examiner has stated "that to the extent that claim 28 is intended to encompass a device wherein the electrode is in contact with the body it is indefinite." Applicant traverse examiners position in that claim 28 does not recite the skin surface or the body as an element. Also, while the claim contains functional language describing the RF energy conduction means delivery means as being adapted to "release the RF energy conduction means to the loose skin surface" and that the "RF energy conduction means delivers energy to the loose skin surface", this is functional language only and the apparatus does not include the skin surface or the body. To the extent that the RF electrode means may be in contact with the skin surface, the applicant points out that "There is nothing inherently wrong with defining some part

of the invention in functional terms" and that "A functional limitation is often used in association with an element...to define a particular capability or purpose that is recited by the element." In this regard, the examiner's attention is directed to MPEP section 2173.05(g).

The examiner has stated that in claims 34-37 it is unclear what further structure is recited thereby; and that in claim 39 there is no function positively recited in the sensor means. In response to this concern, claims 34-37 have been amended to recite further structural limitations. Support for these amendments is found in the claims and specification as filed. Also, claims 39 and 40 have been amended to recite "sensing means" in place of "sensor means".

The examiner has also stated that "Claims 1 and 41 are substantial duplicates." Office action mailed 1/26/99, 2:1-2. Applicant respectfully traverses examiner's position and points out that claims 1 and 41 differ in multiple respects. Specifically the claims differ in the apparatus used, claim 1 recites "providing an energy source with an energy delivery surface", whereas, claim 41 recites " providing an apparatus for applying energy to the loose skin surface, the apparatus including an electrolytic media, a member, and an RF electrode". The claims also differ in the use of a electrolytic media, the third and fourth steps of claim 41 recite "transferring energy from the RF electrode to the electrolytic media to create an energy delivery electrolytic media; releasing the energy delivery electrolytic media from the member to the loose skin surface; ", claim 1 includes neither. The claims further differ in that the fourth step of claim 1 recites "the creation of a reverse thermal gradient"; while there is no such step in claim 41. Clearly in using different apparatus, with different steps, the two claims are not substantial duplicates.

#### Rejections under 35 U.S.C. §102(e)

The Examiner has rejected claims 28-40 as being clearly anticipated by Eggers, et al. but does provide detail on this rejection. Office action mailed 1/26/99, 7:1-3.

The present invention as embodied in claim 28, includes an identification means for detecting a loose skin surface, an RF energy conduction means, an RF energy conduction means delivery means, adapted to receive the RF energy conduction means and release the RF energy conduction means to the loose skin surface. An RF electrode means is coupled to the RF energy conduction means, wherein the RF electrode means transfer energy to the RF energy conduction means and the RF energy conduction means delivers energy to the loose skin surface to create a controlled cell necrosis and tighten the loose skin surface.

Applicant asserts that Eggers '909 teaches away from the current invention in several important respects. First, Eggers teaches a method and apparatus for cutting tissue the present invention does not. This intended function of Eggers is described in the title, abstract and summary of the invention ( lines 56-57 of column 2). Second, Eggers does not teach the use of an RF conduction means such as an electrically

conductive fluid to deliver energy to target tissue. In fact, Eggers explicitly teaches away from the use of an electrically conductive fluid to deliver energy and even states that it is a "central aspect of the invention" not to do so (Col 12, lines 1-4, Col 6 1-4; Col 7, lines 19-22; Col 9, lines 6-9). This is because such the transfer of energy to such a fluid would dissipate power which would be contrary to Eggers explicit teaching "to deliver high energy flux levels" directly to target tissue (ibid). In fact, Eggers states that the use of electrically conductive fluids by prior art apparatus "substantially reduced effectiveness" of cutting and ablation, ( the intended functions of Eggers) because power is dissipated within the electrically conductive fluid. (Col 12, lines 29-37). Moreover, one of the key stated improvements of Eggers over the prior art is its ability not to have energy dissipated from its electrodes (ibid). Also, Eggers does not teach the use of a RF energy conduction means delivery means to deliver an RF energy conduction means such as a electrically conductive fluid.

In summary, the fundamental function of Eggers is cutting and ablating tissue. To accomplish this goal it is Eggers explicitly teaching that "high energy flux levels" are directly delivered to target tissue via electrodes. Because of this teaching, the Eggers apparatus can not and does not include two elements of the present invention: an RF energy conduction means and a RF energy conduction means delivery means. Therefore, for this and the reasons described above, withdrawal of this rejection is respectfully requested.

#### Rejections under 35 U.S.C. §103(a)

The Examiner has rejected claims 1-27 and 41-68 as being obvious over Neefe in combination with Sand ('709). The Examiner states that Neefe teaches a collagen shrinkage method using various types of energy, and that Sand teaches a method of shrinking collagen using light. The Examiner asserts that it would have been obvious to employ various forms of heating energy in the method of Sand, since these are equivalents taught by Neefe, thus producing the claimed method. Office action mailed 1/26/99, 7:4.

These grounds of rejection are respectively traversed. The method taught in the present invention identifies a person suspected of having a loose skin surface and provides an electromagnetic energy delivery device with an energy delivery surface. The energy delivery surface is positioned in contact with the skin surface. A reverse thermal gradient is created, where a temperature of the skin surface is less than a temperature of collagen containing tissue. A sufficient amount of energy is then delivered through the skin surface to the underlying collagen containing tissue to contract at least a portion of the collagen containing tissue with controlled cell necrosis to tighten the loose skin surface.

Neefe does not teach all steps of the present invention and actually teaches away from the invention in several important respects. First, Neefe does not teach delivery of energy through the skin surface, but rather the cornea. There are significant differences in the anatomy, morphology and mechanical and

thermodynamic properties between the skin surface and the cornea (e.g. thermal diffusivity, avascular nature of the cornea, thickness, etc.) which render the methods taught by Neefe wholly unsuitable for treatment of the skin. Moreover, these differences are so significant as to 1) result in unpredictable results in application to the skin, and 2) require the skilled artisan to engage in undue experimentation in order to modify them for treatment of the skin if such modification is possible at all. Another key distinction resulting in unpredictability and requiring undue experimentation is the fact that the cornea is supported/connected on its entire perimeter by the sclera. The present invention does not necessarily include such a limitation, and owing to Bessel function and other mathematical and physical constraints, the collagen contraction occurring in Neefe would be expected to be significantly different from the collagen contraction of tissue in the present invention not so supported. As a result of one or more of these differences, there would be no predictability in combining Neefe with Sand ('709) to practice the current invention and no expectation of success.

Second Neefe does not provide "an electromagnetic energy delivery device with an energy delivery surface" as the present invention does. None of the energy sources recited by Neefe include the recitation of an accompanying energy delivery surface. Instead, Neefe teaches an indirect form of energy delivery by heating a mold *in vitro* and then transferring the mold to the cornea. The mold can not be considered an energy source since all energy must be transferred to it, hence it is an energy sink not a source. Moreover, while Neefe may claim a method for heating the metal mold *in situ*, it does not disclose a specific technique or method for doing so. Owing to the complex heat transfer considerations involved, combined with the significant safety constraints of not injuring the eye, such knowledge was not known to the skilled artisan as of Neefe's filing date and in this respect, Neefe is not enabled.

Also, Neefe is incapable of producing a reverse thermal gradient as is claimed in the present invention even when combined with cooling. This is because Neefe only teaches the delivery of energy to tissue from a heated mold placed on the cornea (tissue) surface. The only form of appreciable energy delivery to the surface under this circumstance is by thermal conduction. Owing to Fourier's law governing conductive heat transfer, a reverse thermal gradient can not be created for conduction alone, even with the presence of simultaneous cooling. That is, both heating by conduction and cooling by conduction travel at the same rate through tissue. Thus, the combination of cooling taught by Sand ('709) with Neefe will render Neefe incapable of performing its originally intended function since cooling will directly offset any heating at the intended tissue treatment site. Therefore, the skilled artisan would have no expectation of success in combining Neefe with Sand ('709).

Furthermore, Neefe does not also teach the use of electrolytic media or RF energy conduction means or RF energy as recited in independent claims 35, 56 and dependent claims 11 and 17. Neefe does not specifically recite the use of RF energy or the transfer of energy from an RF electrode to electrolytic media.

The only form of energy delivery to a tissue surface that Neefe teaches is thermal conduction. All other forms of energy recited by Neefe are used to heat the mold and not the tissue.

Also, Neefe does not teach or suggest contraction of collagen with "controlled cell necrosis" as is taught in independent claims 1 and 35. Neefe only teaches contraction of collagen. Since Neefe only uses the externally heated mold to deliver energy Neefe is incapable of having the necessary control of energy delivery to produce such a controlled cell necrosis. Moreover, owing to Neefe's limited ability to only deliver energy by the heated mold, e.g. conduction, combined with the complex heat transfer consideration involved it would not be obvious to the skilled artisan how to modify the method taught by Neefe to produce such a controlled cell necrosis. The difficulty in doing so is compounded by the significant difference in anatomy, morphology and thermal properties between the cornea and the skin and underlying fat tissue. As described above, such difference include the fact the cornea is avascular, has a different thermal diffusivity, composition and thickness versus the skin.

Finally, Neefe appears to lack enabling disclosure because the mold disclosed in Neefe is not configured to apply adequate force onto the cornea of the eye to achieve the reshaping effect. Research has shown the cornea is extremely strong with a Young's (elastic) modulus of the cornea to be greater than 725 lbs/(inch<sup>2</sup>) or  $5 \times 10^6$  Newtons/m<sup>2</sup>. This means to displace the cornea even 0.01<sup>2</sup> inches requires the application of 7.25 lbs of force. Neefe does not teach the application of this or any external force to cornea including the inclusion of any examples. The only force that would be applied to the cornea would be a passively applied force due to the weight of the mold on the eye which would could not realistically be greater than several grams (e.g. five grams or 0.01 lbs). Even accounting for softening that may occur as a result of heating or chemical treatment displacement, it seems unlikely that the cornea would soften by the several orders of magnitude necessary to allow the weight of the mold alone to cause even minor deformation. Moreover, Neefe does not disclose or provide any examples of how much softening does occur so the skilled artisan is left guessing. Also Neefe does not disclose any example of how much external force to apply to the cornea in order to achieve a desired amount of corneal deformation, or how the force should be applied. This information is critical to the function of Neefe yet absent. Owing to skill in the art at the time, the elucidation of such information would have required the skilled artisan to engage in substantial undue experimentation. While Neefe does mention the use of intraocular pressure to push the cornea into the mold, this approach is critically flawed because: 1) Neefe does not teach the use of an externally applied force to hold the mold in place to counter the intraocular force, 2) Neefe does not provide working examples or data to prove that this force is sufficient 3) the intraocular force is insignificant compared to the forces necessary to deform the cornea. Because of this lack of enablement, together with the other deficiencies discussed herein, the skilled artisan

would not and could not use Neefe in combination with Sand ('709) to practice the current invention. For these and the reasons described above, withdrawal of this rejection is respectfully requested.

Provisional Rejections under Judicially Created Doctrine of Obviousness-Type Double Patenting

The Examiner has provisionally rejected the following claims under the judicially created doctrine of obviousness-type double patenting over the commonly owned applications as set forth below:

claims 1-27 and 41-68 over claims 1-44 of co-pending application no. 09/003,120;

claims 1-27 and 41-68 over claims 1-21 and 35-60 of co-pending application no. 09/003,423;

claims 1-27 and 41-68 over claims 1-34 and 56-89 of copending application no. 09/003,180;

claims 1-27 and 41-68 over claims 55-65 of copending application no. 08/942,274;

claims 1-27 and 41-68 over claims 31-54 of copending application no. 08/990,494;

claims 1-27 and 41-68 over claims 1-3, 5-10, 12-13, 15-29 of copending application no. 08/825,443;

claims 1-27 and 41-68 over claims 1-8, 12-14, 16-20 and 55-61 of copending application no. 08/583,815;

claims 28-40 over claims 1, 3-4, 12-14, 21-29, 35-38 and 46-60 of copending application no. 08/827,237;

claims 28-40 over claims 22-34 of copending application no. 09/003,423;

claims 28-40 over claims 35-55 of copending application no. 09/003/180;

claims 28-40 over claims 1-54 of copending application no. 08/942,274; and

claims 28-40 over claims 1-30 of copending application no. 09/990,494.

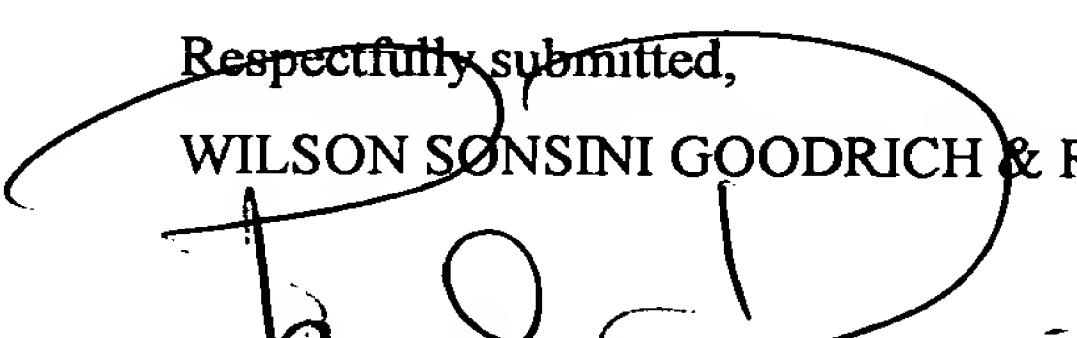
Applicant submits terminal disclaimers to overcome the examiner's objections.

CONCLUSION

It is submitted that the present application is in form for allowance, and such action is respectfully requested.

The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, to Deposit Account No. 23-2415 (Docket No. 16904-727). A duplicate copy of this paper is enclosed.

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Respectfully submitted,  
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